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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,859	09/12/2003	Jong-Soo Woo	DE-1508	8650

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	**PAPER NUMBER**
1617	
MAIL DATE	**DELIVERY MODE**
12/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/660,859	WOO ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,7-9,12 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 5, 7-9, 12-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments over the 35 USC 102(b) rejection over Woo et al. have been considered and are not considered persuasive. Applicants argue that the composition of Woo et al. is completely different from the present composition because the reference does not teach that the acidifying agent forms a microemulsion in the body fluid when orally administered.

In response to the above argument, it is noted that claims 1, 3, 5, 7-9 and 12-13 are drawn to a composition and therefore are being treated as a composition. Furthermore, though Woo does not specifically state that the phosphoric acid (acidifying agent) forms a microemulsion in the body fluid when orally administered, it is noted that this is a property of the phosphoric acid and it is inherent that it will perform the same function once in the body. Accordingly, the rejection is maintained.

Applicant's arguments over the 35 USC 102(b) rejection over Baert have also been considered and they are not found to be persuasive. Applicants argue that Baert teaches that itraconazole may be present in the form of an acid addition salt generated using an appropriate acid. Applicants further argue that the composition of Baert is different from the present composition because the present composition forms microemulsion in the body fluid when orally administered.

In response to the above argument, Baert teaches that the acid addition forms of the itraconazole compounds are obtained by reaction of the base form with the appropriate acid. Likewise in the present application, the itraconazole is being mixed with the acidifying agent. Both compositions are being mixed with phosphoric acid or

hydrochloric acid, leading to the rejection. As discussed above, though Baert does not specifically state that the phosphoric acid forms a microemulsion in the body fluid when orally administered, it is noted that this a property of the phosphoric acid and it is inherent that it will perform the same function once in the body. Accordingly, the rejection is maintained.

Applicant's arguments over the 35 USC 103 rejection have been considered and are not found persuasive. Applicants argue that the combination of Baert and Lee does not suggest adding an acidifying agent to form a microemulsion in the body fluid. Applicants further argue that their composition has the unexpected result of a higher amount of dissolved itraconazole than that of commercially available preparations and refer back to their Declaration.

In response to the above arguments, as discussed above, forming a microemulsion in the body is a property of the composition. If the prior art teaches the same composition, it will be inherent that the property of forming a microemulsion will also occur. To address the argument that the present composition has the unexpected result of having a higher amount of dissolved itraconazole compared to commercially available products, the Declaration showed data comparing the present compound with the commercially available Sporanox and not the compositions of Baert or Woo. Therefore, the claim of unexpected results absent a showing of data is not persuasive. Accordingly, the rejection is maintained.

The following modified rejections are being given below.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 7-8 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Woo et al. (US Patent 6,039,981).

Woo et al. teach oral compositions comprised of itraconazole and an acidifying agent (phosphoric acid; Col. 2, lines 17-20), an amphiphilic additive (propylene glycol; Col. 2, lines 59-64), a surfactant (polyoxyethylene-sorbitan-fatty acid esters; Col. 2, lines 48-50) and an oil (polyoxyethylene glycolated natural or hydrogenated vegetable oils; Col. 2, lines 44-47) all meeting the limitations of claims 1 and 7- 8. Because the composition of the prior art and the composition of the present claims are comprised of the same components, it is inherent that they share the same physical properties, such as viscosity of claim 3. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

It is respectfully pointed out that instant claims 12-13 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability

of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 7 rejected under 35 U.S.C. 102(b) as being anticipated by Baert et al. (WO 97/44014).

Baert et al. teach a glassy and highly viscous pharmaceutical composition comprising of itraconazole, an amphiphilic additive (e.g., propylene glycol), a surfactant (e.g., hydroxymethylcellulose (HPMC) and an oil (e.g., hydrogenated vegetable oil; Pg. 5, lines 4-17; Pg. 12, lines 25-37 – Pg. 13, lines 1-4). Baert also teaches that itraconazole comprises the free base form and pharmaceutically acceptable addition salts formed by reaction with appropriate acids such as hydrochloric acid and phosphoric acid (Pg. 1, lines 34-38 – Pg. 2, lines 1-4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5, 7-9 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baert et al. (WO 97/44014) in view of Lee et al. (US Pg-Pub 2004/0248901).

Baert et al. teach a pharmaceutical composition as discussed above. Baert teach that the bioavailability of the composition in fasted and fed states is comparable (Pg. 3, lines 33-34). Such a teaching renders the bioavailability ratio before and after food ingestion at 0.8 or higher (of claim 1) obvious because the comparable bioavailability in fasted and fed states can be construed as a ratio of 1:1.

Baert et al. does not teach the viscosity of the composition or the ratios of each component comprising the composition, and tocopherol as an oil used in the composition.

Lee et al. teach similar viscous compositions comprised of itraconazole (paragraph 0025). The composition is further comprised of tocopherol (meeting the limitation of claim 9; paragraph 0031). The similar composition is comprised of a surfactant (polyoxyethylene sorbitan monostearate; paragraph 0027) and an amphiphilic (transcutol; paragraph 0029).

Furthermore, it is obvious to vary and/or optimize the amount of itraconazole provided in the composition, according to the guidance provided by Baert et al., to provide a composition having the desired properties such as the desired viscosity, desired ratios of itraconazole and acidifying agent, amphiphilic, surfactant and oil. It is

noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teachings of Baert et al., which teaches a pharmaceutical composition comprising itraconazole, an acidifying agent (e.g. hydrochloric or phosphoric acid), an amphiphilic additive (e.g. propylene glycol), a surfactant and an oil (e.g., hydrogenated vegetable oil), and also a dosage form in which the bioavailability of itraconazole in the fasted and fed state in a mammal is comparable, with the teachings of Lee et al. who teach that an oil such as tocopherol can be used in such a composition. It would have been further obvious to vary and/or optimize the amount of itraconazole to achieve the desired viscosity and ratios of itraconazole to other ingredients in the composition. Accordingly, one having ordinary skill in the art at the time the invention was made would have been motivated to utilize the composition of Baert et al. and utilize tocopherol of Lee et al. and adjust the ratios of itraconazole, acidifying agent, amphiphilic additive, surfactant, and oil in an effort to obtain a more viscous composition with an increased bioavailability.

It is respectfully pointed out that instant claims 12-13 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is

unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER